INTERNATIONAL APPLICATION PUBLISHED UNDER THE INTERNATIONAL PATENT COOPERATION TREATY (PCT)
World Organization for Intellectual Property
International Office

Date of International Publication: **June 7, 2001**
International Publication No.: **WO 01/39751 A1**

International Patent Classification: **A61K 9/48, 9/20**
International Reference No.: PCT/EP00/11922
Date of International Application: November 29, 2000
Language of submission: German
Language of publication: German
Priority Data : 199 58 007.3 December 2, 1999 DE
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Contracting States (national): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW.

Contracting States (regional): ARIPO patent GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published With an international search report.

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Title: INJECTION MOLDING METHOD FOR (METH)ACRYLATE COPOLYMERS HAVING TERTIARY AMMONIUM GROUPS.

Abstract: The invention relates to a method for producing molded bodies by injection molding which comprises the following steps: a) melting a (meth)acrylate copolymer that is composed of 30 to 80% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 70 to 20% by weight of (meth)acrylate monomers with a tertiary ammonium group in the alkyl radical. The (meth)acrylate copolymer used is present in a mixture with 1 to 70% by weight of a softener and a desiccating agent in a ratio of 1:1 to 1:20 and with 0.05 to 5% by weight of a mold-release agent. In addition, other conventional additives or adjuvants and optionally a pharmaceutically active substance can be present in the mixture. Before melting, the mixture has a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C. In step b), the mixture is degassed in the thermoplastic state at temperatures of at least 120°C, thereby reducing the content of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C to not more than 0.5% by weight. The molten and degassed mixture is c) injected into the mold cavity of an injection mold, the mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer. The molten mixture is then cooled off and the resulting molded body is removed from the mold.

Injection-molding method for (meth)acrylate copolymers having tertiary ammonium groups

The invention relates to a procedure for producing molded bodies by injection molding, the molded bodies themselves and their use for pharmaceutical purposes.

Prior Art

US 4,705,695 describes a method of coating pharmaceutical formulations with an aqueous coating agent containing a water-soluble (meth)acrylate copolymer with tertiary amino groups and with a water-insoluble neutral polymer as a binder. The solubility of the (meth)acrylate copolymer, consisting, for example, of equal percentages of methylmethacrylate and dimethylaminoethylmethylacrylate, is caused by stirring in powder form with particle sizes under 0.25 mm into water with the simultaneous addition of an acid. An insoluble copolymer, e.g., from methylmethacrylate and ethylacrylate (70:30) is used as a binder. The production of the coating solution is relatively expensive. Due to the acid content, the coating has an unpleasant taste. Corresponding films dissolve both in artificial gastric juice and in water in less than two minutes.

EP 0,704,207 A2 describes thermoplastic synthetics for medicine containers that are soluble in intestinal juice. This involves mixed polymers from 16 to 40% by weight acrylic or methacrylic acid, 30 to 80% by weight methacrylate and 0 to 40% by weight other alkyl esters of acrylic acid and/or methacrylic acid.

In the example, corresponding mixed polymers are melted at 160°C and are mixed after the addition of 6% by weight glycerine monostearate. The mixture is broken and ground to a powder. The powder is loaded into the feed chamber of an injection transfer mold and injected at 170°C under a pressure of 150 bar through an opening 0.5 mm wide into the mold cavity. After cooling, bubble-free, slightly opaque, thin-walled capsules for medicine are obtained. Special steps for removing low-boiling components immediately before injection mold processing are not disclosed.

Task and Solution

The task was seen to be to provide a procedure which allows familiar (meth)acrylate copolymers having monomers with tertiary ammonium groups to be processed by the injection molding process. In this way molded bodies must be obtained that have gastric acid soluble properties and meet high mechanical requirements so that they can be used, for example, as capsules (two-part capsules) that act as containers for pharmaceutically active substances.

Method of Producing Molded Bodies by Injection Molding

with the following steps:

a) Melting a (meth)acrylate copolymer which comprises 30 to 80% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 70 to 20% by weight (meth)acrylate monomers with a tertiary ammonium group in

the alkyl radical,

the (meth)acrylate copolymer being present in a mixture of 1 to 70% by weight of a softener and a desiccating agent in a ratio of 1:1 to 1:20,

the mixture containing at least 1% by weight of a softener,

and containing 0.05 to 5% by weight of a mold-release agent, and

other conventional additives or adjuvants and optionally a pharmaceutically active substance also possibly being contained in the mixture, and the mixture, before melting, having a content of more than 0.5% by weight of low boiling components with a vapor pressure of at least 1.9 bar at 120°C.

b) Degassing the mixture in the thermoplastic state at temperatures of at least 120°C, which lowers the content of low boiling components with a vapor pressure of at least 1.9 bar at 120°C to no more than 0.5% by weight.

c) Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer, cooling the molten mixture and removing the resulting molded body from the mold.

The method of the invention allows new injection-molded bodies to be obtained which meet the requirements of high mechanical strength and temperature stability.

Embodiment of the Invention

The method of the invention for producing molded bodies by injection molding is divided into steps a), b) and c).

Step a)

Melting a (meth)acrylate copolymer comprising 30 to 80% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 70 to 20% by weight of (meth)acrylate monomers with a tertiary ammonium group in the alkyl radical, the (meth)acrylate copolymer used being present in a mixture having 1 to 70% by weight of a softener and a desiccating agent in a ratio of 1:1 to 1:20, preferably 1:1 to 1:10, and ideally 1:1 to 1:4, with at least 1% by weight of softener being present, and having 0.05 to 5% by weight, and preferably 0.1 to 3% by weight, of a mold-release agent. In addition, other conventional additives or adjuvants and optionally a pharmaceutically active substance may be present in the mixture. Before melting, the mixture has a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C.

The copolymer, which is in the form of a granulate or powder, is preferably melted in an extruder at a temperature of 80 to 250°C.

The (Meth)acrylate Copolymer

The (meth)acrylate copolymer comprises 30 to 80% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 70 to 20% by weight (meth)acrylate monomer with a tertiary ammonium group in the alkyl radical.

Suitable monomers with functional tertiary ammonium groups are listed in US 4,705,695, column 3, line 64, through column 4, line 13. Special mention is given to dimethylaminoethylacrylate, 2-dimethylaminopropylacrylate, dimethylaminopropylmethacrylate, dimethylaminobenzylacrylate, dimethylaminobenzylmethacrylate, (3-dimethylamino-2,2-dimethyl)propylacrylate, dimethylamino-2,2-dimethyl)propylmethacrylate, (3-diethylamino-2,2-dimethyl)propylacrylate and diethylamino-2,2-dimethyl)propylmethacrylate. Dimethylaminoethylmethacrylate is especially preferred.

The content of monomers with tertiary ammonium groups in the copolymer may, beneficially, be between 20 and 70% by weight, and preferably between 40 and 60% by weight. The percentage of C_1 to C_4 alkyl esters of acrylic or methacrylic acid is 70 to 30% by weight. Methylmethacrylate, ethylmethacrylate, butylmethacrylate, methylacrylate, ethylacrylate and butylacrylate must be mentioned.

A suitable (meth)acrylate copolymer with tertiary amino groups can, for example, be made up of 20 to 30% by weight methylmethacrylate, 20 to 30% butylmethacrylate and 60 to 40% by weight dimethylaminoethylmethacrylate.

A suitable commercial (meth)acrylate copolymer with tertiary amino groups is made up, for example, from 25% by weight methylmethacrylate, 25% by weight butylmethacrylate and 50% by weight dimethylaminoethylmethacrylate (EUDRAGIT® E100).

The copolymers are obtained in the conventional manner by radical substance, solution, pearl or emulsion polymerization. Before processing, they must be made to match the particle size range of the invention by grinding, drying or spraying processes. This can be done by simple breaking of extruded and cooled granulate strands or hot sprueing.

The use of powders may be beneficial, especially when mixing with other powders or liquids. Suitable equipment for producing the powder is familiar to the specialist, for example, air jet mills, pinned disk mills, fan mills. Optionally, corresponding screening steps can be used. A suitable mill for large industrial quantities is, for example, a counter jet mill (Multi No. 4200), which operates at approx. 6 bar.

For powders, the mean particle size can be determined as follows:
- By air-jet screening for simple division of the ground product into a few fractions. This method is somewhat less precise in this range of measurement than the alternatives. At least 70, and preferably 90%, of the particles relative to the mass (mass distribution) must be in the 1 to 40 µm range, preferably between 5 and 35, and ideally between 10 and 20 µm.

One highly suitable method of measurement is laser diffraction for determining the particle size distribution. Commercial units allow measurement in air (Malvern Co. S3.01 Particle Sizer) or preferably in liquid media (LOT Co., Galai CIS 1). The prerequisite for measurement in liquids is that the polymer does not dissolve in it or the particles do not change in another way during measurement. One suitable medium is, for example, a highly diluted (approx. 0.02%) aqueous polysorbate 80 solution.

Mixtures

The (meth)acrylate copolymer is present in a mixture with 1 to 70% by weight of a softener and a mold release agent in a ratio of 1:1 to 1:20, preferably 1:1 to 1:10, and ideally 1:1 to 1:4. Optionally, the mixture may contain other conventional pharmaceutical adjuvants, for example in a percentage of 0.001% by weight to 30% by weight relative to the (meth)acrylate copolymer.

To control the release of active substance, it may be beneficial in some cases to mix in other polymers. The percentage of other polymers in the mixture is no more, however, than 20% by weight, preferably no more than 10% by weight and ideally 0.5% by weight, relative to the (meth)acrylate copolymer.

Examples of such other polymers are: polyvinyl pyrolidones, polyvinyl alcohols, anionic (meth)acrylate copolymers from methylmethacrylate and/or ethylacrylate and methacrylic acid (EUDRAGIT® L 100, EUDRAGIT® S 100, EUDRAGIT® L 100-55), anionic (meth)acrylate copolymers from methylmethacrylate, methylacrylate and methacrylic acid, carboxymethyl cellulose salts, hydroxypropyl cellulose (HPMC), neutral (meth)acrylate copolymers from methylmethacrylate and ethylacrylate (dry substance from EUDRAGIT® NE 30D), copolymers from methylmethacrylate and butylmethacrylate (PLASTOID® B) or (meth)acrylate copolymers with quaternary ammonium groups (EUDRAGIT® RL and EUDRAGIT® RS respectively).

One or more pharmaceutically active substances which do not decompose at the processing temperature may also be present.

The medicines used in the invention (pharmaceutical substances) are intended to be applied in the human or animal body to

1. heal, alleviate, prevent or identify diseases, ailments, bodily injury or pathological complaints;

2. to reveal the condition, state or functions of the body or mental states;

3. to replace substances or bodily fluids produced by the human or animal body;

4. to fend off, eliminate or render harmless pathogens, parasites or foreign substances; or

5. to influence the condition, state or functions of the body of mental states.

Currently used medicinal substances can be found in reference books such as, for example, the Red List or the Merck Index.

In the invention, all substances can be used which have the desired therapeutic effect as defined above and possess sufficient stability and the ability to penetrate through the skin.

Important examples (groups and individual substances) include but are not limited to the following:

Analgesics,
Antiallergics, antiarrhythmics,
Antibiotics, chemotherapeutics, antidiabetics, antidotes,
Antiepileptics, antihypertensives, antihypotensives,
Anticoagulants, antimycotics, antiphlogistics,
Beta receptor blockers, calcium antagonists and ACE inhibitors,
Broncholytics/antiasthmatics, cholinergics, corticoids (internal),
Dermatics, diuretics, enzyme inhibitors, enzyme preparations and transport proteins,
Expectorants, geriatrics, antipodagrics, influenza remedies,
Hormones and their inhibitors, hypnotics/sedatives, cardiacs, lipid lowerers,
Parathyroid hormones/calcium metabolism regulators,
Psychopharmaceuticals, sex hormones and their inhibitors,
Spasmolytics, sympatholytics, sympathomimetics, vitamins,
Wound treatment agents, cytostatics.

Examples of substances suitable for filling molded bodies (capsules) or for incorporation into the molded bodies are: ranitidine, simvastatin, enalapril, fluoxetine, amlodipine, amoxicillin, sertraline, nifedipine, ciprofloxacin, acyclovir, lovastatin, epoetin, paroxetine, captopril, nabumetone, granisetron, cimetidine, ticarcillin, triamterene, hydrochlorothiazide, verapamil, paracetamol, morphine derivatives, topotecan or the pharmaceutically used salts.

Softeners: Substances suitable as softeners usually have a molecular weight of between 100 and 20,000 and contain one or more hydrophilic groups in the molecule, e.g., hydroxyl, ester or amino groups. Citrates, phthalates, sebacates and castor oil are suitable. Examples of suitable softeners are citric acid alkylester, glycerine ester, phthalic acid alkylester, sebacic acid alkylester, sucrose ester, sorbitane ester, dibutyl sebacate and polyethylene glycols 4000 to 20,000. Preferred softeners are tributyl citrate, triethyl citrate, acetyltriethyl citrate, dibutyl sebacate and diethyl sebacate. The amount used is between 1 and 35, preferably 2 to 10% by weight relative to the (meth)acrylate copolymer.

Desiccant (anti-adhesion agent): Desiccants have the following properties: they affect large specific surfaces, are chemically inert, are readily pourable and finely divided. Due to these properties, they can be effectively homogeneously distributed in molten masses and lower the adhesiveness of polymers which contain highly polar comonomers as functional groups.

Examples of disiccants are:

Aluminum oxide, magnesium oxide, kaolin, talcum, silicic acid (aerosils), barium sulfate, soot and cellulose.

Parting Agents (Mold Release Agents)

Mold release agents must be added in an amount of 0.05 to 5% by weight, preferably 0.1 to 3% by weight, relative to the copolymer.

Unlike desiccants, parting agents have the property of reducing the adhesive strength between the molded parts and the wall of the die in which the molded part is produced. This makes it possible to produce molded parts which do not break and are not geometrically deformed when removed from the mold. Parting agents are usually somewhat or completely incompatible with the polymers in which they are particularly effective. Due to the partial or total incompatibility when the melt is injected into the mold cavity, there is a migration into the transition interface between die wall and molded part.

For parting agents to be able to migrate particularly effectively, the melting point of the parting agent must be 20°C to 100°C below the processing temperature of the polymer.

Examples of parting agents (mold release agents) are: esters of fatty acids or fatty acid amides, aliphatic, long-chained carboxylic acids, fatty alcohols and their esters, montan or paraffin wax and metal soaps, with special mention for glycerol monostearate, stearyl alcohol, glycerol behenic acid ester, cetyl alcohol, palmitic acid, carnauba wax, beeswax, etc.

Other Conventional Pharmaceutical Adjuvants : These include, for example, stabilizers, dyes, antioxidants, wetting agents, pigments, brighteners, etc. They serve primarily as processings aids and are intended to ensure a reliable and reproducible production process as well as long-term storage stability. Other conventional pharmaceutical adjuvants may be present in amounts of 0.001 to 30% by weight, preferably 0.1 to 10% by weight.

Low-Boiling Components

In its commercial form, the familiar (meth)acrylate copolymer almost always has a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C. The standard amounts of these components are in the range of 0.7 to 2.0% by weight. The low-boiling components primarily involve water that is absorbed from the air humidity.

Step b)

Degassing the mixture at temperatures of at least 120°C, preferably at a minimum of 150°C and a maximum of 250°C, whereby the content of low-boiling components with a minimum vapor pressure of 1.9 bar at 120°C is reduced to a maximum of 0.5% by weight, preferably a maximum of 0.2% by weight, and ideally a maximum of 0.1% by weight. This prevents any sudden undesired out-gassing during the injection molding process in step c) that would lead to the

formation of bubbles or foaming within the molded body being created that would make it unusable.

Since the (meth)acrylate copolymer has a glass transition temperature in the 50°C range, low-boiling components cannot usually be removed by simple drying at a high temperature which would sinter or film over the copolymer in an undesirable manner..

Degassing step b) is therefore performed preferably by extrusion drying by means of an extruder with a degassing zone or by means of injection molding equipment with an injection molding die with a preceding degassing opening.

The degassed extruded material obtained by extrusion drying in an extruder with a degassing zone can be fed directly to the injection molding machine with no further steps to remove low-boiling components and can be processed directly into molded bodies.

In the case of degassing on an injection molding installation with a degassing opening in the injection molding cylinder, degassing is performed before the molten plastic mass is pressed into the injection molded shape by means of said degassing opening in the injection molding cylinder.

Step c)

Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C, preferably at least 12°C, and better, at least 15°C, and ideally at least 25°C or even at least 35°C below the glass transition temperature of the (meth)acrylate copolymer, cooling the molten mixture and removing the resulting molded body from the mold.

The thermoplastic processing is performed in the familiar manner by means of an injection molding machine at temperatures in the range of 80 to 220°C, especially between 120°C and 160°C and at pressures of 60 to 400 bar, preferably 80 to 120 bar.

The mold temperature is, at glass transition temperatures of the (meth)acrylate copolymers used, correspondingly lower in a range of 40°C to 80°C, for example at a maximum of 30 or a maximum of 20°C so that the copolymer can be solidified a short time after the injection process in the mold and the finished molded body can be removed from the mold.

The molded bodies can be removed from the mold cavity of the injection molding die without breaking and have an even, compact, blemish-free surface. The molded body is distinguished by a mechanical stability under load or elasticity and resistance to breakage.

It has, in particular, an ISO 179 impact strength measured on test specimens of at least 1.0 KJ/m^2, preferably at least 1.5 KJ/m^2, and ideally at least 2.0 KJ/m^2.

The VST (A10) thermal stability, measured on test specimens according to ISO 306, is approximately between 30°C and 60°C.

The molded bodies obtained by the invention may have, for example, the form of a capsule, part of a capsule, e.g., a capsule half, or a two-part capsule, serving as a container for a pharmaceutically active substance. Active substances obtained in binders can be inserted in the form of pellets, for example, and the two capsule halves can then be joined together by adhesion, or by laser, ultrasonic or microwave welding, or by means of a snap connection.

According to this method, capsules made of different material (e.g., gelatines, anhydrolyzed starch, HPMC or other methacrylates) can be combined with each other. The molded body may therefore also be part of a dosage unit.

Other forms, such as tablets or lense geometries, are possible. In this case the compound used for the injection molding already contains the pharmaceutical substance. In the final form, the active substance is distributed as evenly as possible in crystalline (solid dispersion) or dissolved (solid solution) form.

EXAMPLES

Example 1: Molded Body Soluble in Gastric Juice / Degassing in Extruder

A mixture (compound) according to the invention was produced on a twin-screw extruder (Leistritz LMS 30.34).

10 kg granulate of a methacrylate copolymer from 25% by weight methylmethacrylate, 25% by weight butylmethacrylate and 50% by weight dimethylaminoethylmethacrylate (EUDRAGIT® E100) were fed per hour into the feed zone of the twin-screw extruder via a gravimetric dosing unit. 20% by weight talcum (desiccant) and 0.25% by weight stearyl alcohol (mold release agent) were also fed continuously into the feed zone of the twin-screw extruder via another gravimetric dosing unit.

The components were drawn into the extruder at a screw speed of 120 rpm, the polymer was plastified and the talcum was homogeneously mixed into the molten mass. The set melting temperature was 160°C. There is an opening in the cylinder wall after a length of 50% of the total length of the twin-screw extruder; triethyl citrate is pumped in through this opening by a membrane pump in an amount of 5% by weight relative to the amount of polymer. A degassing opening which opens to the environment is located in the screw cylinder after a mixing zone for the homogenization of the mixture. Vapor can be observed coming out of the degassing zone.

Four strands were molded from the extruder by means of a nozzle, drawn off via a cooled plate and cut into granulate. The moist granulate content obtained was found to be 0.05% according to the K. Fischer method. Examination of the non-extruded starting granulate revealed a water content of 0.94%.

To improve flowability and reduce adhesiveness, the granulate was vigorously mixed in a mixing drum after the addition of 0.05% talcum, so that the granulate particles had a powdered surface.

Injection Molding Processing of the Granulate Obtained

The mixture (compound) obtained was put into the funnel of an injection molding machine (Allrounder 221-55-250, Arburg Co.) and molded bodies were injection molded.

The following temperatures were set on the injection molding machine: zone 1 (feed zone): 70°C; zone 2: 120°C; zone 3: 160°C; zone 4: 160°C; zone 5 (nozzle): 130°C. Injection pressure 60 bar, dwell pressure 50 bar, dynamic pressure 5 bar. Die temperature: 17°C

A platelet 60 x 45 x 1 mm was injection-molded as a molded body. Platelets that had no streaks and a blemish-free smooth surface were produced. The platelets could be removed from the mold with no problem and are geometrically stable.

Example 2: (Example for Comparison)

A compound was produced as in Example 1, with the degassing opening at the end of the extruder being closed off. A moisture content of 0.63% was found in the granulate obtained from the extruder.

The granulate was placed on the injection molding machine as in Example 1 and processed with the parameter setting being respected.

The molded bodies obtained showed streaking and surface defects and did not meet the requirements.

After 7 molded bodies were produced, there were problems with the granulate input on the injection molding machine. It was found that condensed moisture had collected in the input area of the screw and had led to failure of the solids feed mechanism.

Example 3: (Example for Comparison / No Desiccant)

A mixture was produced as described in Example 1 with the addition of 0.25% by weight stearyl alcohol but no desiccant. The granulate obtained was fed into the injection molding machine and processed as described in Example 1. It was not possible to produce a molded part. The platelet sticks in the injection molding die and cannot be removed from the mold.

Example 4: Degassing in an Injection Molding Machine

A mixture (compound) was produced as described in Example 1, with the degassing opening being closed off. The moisture content of the granulate obtained was found to be 0.57% by the K. Fischer method. The injection molding unit on the injection molding machine was replaced with a unit with a degassing

opening in the screw cylinder. The granulate was then processed into molded bodies with no problem.

Example 5:

A mixture was produced as indicated in Example 1. Capsules with a length of 16 mm, a mean outside diameter of 6.8 that was reduced to 4 mm toward the closed end and a wall thickness of 0.6 mm were injection-molded on an injection-molding machine (Boy Micro 22 model).

After the molten material was injected and after a dwell time of 6 seconds followed by a cooling time of 18 seconds, the mold was opened and the capsules were removed. The capsules could be removed from the mold without breaking. Mechanically stable, opaque to whitish capsules were obtained.

Testing the Solubility in Gastric Juice of the Capsules Produced

The capsules produced were tested for dissolution behavior in accordance with Pharm. Eur in a paddle device with a rotation speed of 100 rpm. In artificial gastric juice (0.1 n hydrochloric acid, pH 1.2), the capsule dissolved after 2 hours; only a slight swelling associated with a whitish clouding was observed in demineralized water, while there was no change in phosphate buffer pH 7.5 after 2 hours.

CLAIMS

1. Method of producing molded bodies by injection molding

with the steps

a) Melting a (meth)acrylate copolymer which comprises 30 to 80% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 70 to 20% by weight (meth)acrylate monomers with a tertiary ammonium group in the alkyl radical,

the (meth)acrylate copolymer being present in a mixture having 1 to 70% by weight of a softener and a desiccating agent in a ratio of 1:1 to 1:20,

the mixture containing at least 1% by weight of a softener,

and containing 0.05 to 5% by weight of a mold-release agent, and

other conventional additives or adjuvants and optionally a pharmaceutically active substance also being contained in the mixture, and the mixture, before melting, having a content of more than 0.5% by weight of low boiling components with a vapor pressure of at least 1.9 bar at 120°C.

b) Degassing the mixture in the thermoplastic state at temperatures of at least 120°C, which lowers the content of low boiling components with a vapor pressure of at least 1.9 bar at 120°C to no more than 0.5% by weight.

c) Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer, cooling the molten mixture and removing the resulting molded body from the mold.

2. Method as in Claim 1, characterized in that degassing step b) is performed by extrusion drying by means of an extruder with a degassing zone or by means of an injection-molding installation with a degassing opening preceding the injection-molding die in the injection-molding cylinder.

3. Injection-molded body that can be produced with a method as in Claim 1 or 2.

4. Molded body as in Claim 3, characterized in that it has an impact strength of at least 1.5 KJ/m^2 in accordance with ISO 179.

5. Molded body as in Claim 3 or 4, characterized in that a capsule, part of a capsule or part of a dosage unit is involved.

6. Molded body as in Claim 3 or 4, characterized in that it contains a pharmaceutically active substance.

7. Use of a molded body as in one or more of Claim 3 through 6 as a container or carrier for a pharmaceutically active substance.